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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,441,168
Filed: November 23, 2010

ORDER TO SHOW CAUSE

This is an order to show cause based on the apparent untimely filing of the present application for patent term extension of U.S. Patent No. 6,441,168 ("the '168 patent") under 35 U.S.C. § 156.

In section 156(a) of title 35, several eligibility requirements for a patent term extension are found. In addition to the requirements found in section 156(a), the PTE application must be timely filed. Section 156(d)(1) provides, in relevant part:

> To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period *beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred* for commercial marketing or use.

35 U.S.C. § 156(d)(1) (emphasis added). The "beginning on" language makes clear that the triggering date for filing a PTE application is the day of FDA approval, *i.e.*, the date of the NDA approval letter. The triggering date is not the day after FDA approval. In other words, the first day of the sixty-day period within which an applicant must submit a PTE application is the day of FDA approval. The day after FDA approval is considered to be the second day in the sixty-day application window.

Additionally, the USPTO's regulation implementing section 156(d)(1) mirrors the language of section 156(d)(1): "The application is submitted **within the sixty day period beginning on the date the product first received permission for commercial marketing or use** under the provision of law under which the applicable regulatory review period occurred . . . ." *See* 37 C.F.R. § 1.720(f) (emphasis added).

Based on the plain language of section 156(d)(1) and Rule 1.720(f), the FDA's grant of permission for commercial marketing or use triggers the time period for submission of a patent term extension application. The phrases used in section 156(d)(1) and Rule 1.720 to define the time period for submitting a patent term extension application, *i.e.*, "within" and "beginning on," are clear. *See Unimed, Inc. v. Quigg*, 888 F.2d 826, 828 (Fed. Cir. 1989) (characterizing the language used in section 156(d)(1) as "crystal clear"). Thus, under both section 156(d)(1) and Rule 1.720(f), a PTE applicant has sixty days to submit a PTE application; the first day of that sixty day period begins on the date granted permission for commercial marketing or use of the product which was subject to the applicable regulatory review period.

Here, Applicant received FDA approval on September 24, 2010, triggering the start of the sixty-day period for filing its PTE application and making its PTE application due on or before November 22, 2010. Applicant did not, however, file its PTE application until November 23, 2010, one day late.

It is noted that the court in *The Medicines Company v. Kappos*, 731 F. Supp. 2d 470 (E.D. Va. 2010), provided some guidance on when the trigger of the time period in section 156(d)(1) commences. The court determined that the language in 156(d)(1), "beginning on the date" should be given a business day interpretation, even though, to date the USPTO had given the language a calendar day interpretation. The court's rationale rested on the fact that the exact same language in the remedial statute, *i.e.*,"beginning on the date," when interpreted by the Food and Drug Administration (FDA) in its administration of 156(g)(1)(B)(ii) (to determine New Drug Application (NDA) submission dates), is given a business day interpretation. *Medicines* at 482. The court further points out that a business day interpretation ensures that applicants do not lose a portion of the period Congress granted them [to file an extension application]. *Medicines* at 483. Thus, the court held that since The Medicines Company received notice of their NDA approval from FDA after the close of FDA's business, *i.e.*, after 4:30 PM EST, then the time period which is "beginning on the date" in section 156(d)(1) starts on the next business day.

Here, no evidence has been made of record indicating that Applicant received notice of its NDA approval from FDA after FDA's close of business, *i.e.*, after 4:30 PM EST. Therefore, without any such evidence, the USPTO presumes that the notice of NDA approval was transmitted to Applicant on September 24, 2010 during FDA's normal business hours. Thus, Applicant filed its PTE application one day late, and the eligibility requirement set forth in section 156(d)(1) does not appear to be satisfied and the '168 patent appears ineligible for patent term extension for this reason.

Applicant has **ONE MONTH** from the date of this letter in order to file a response indicating that the application has been timely submitted. Extensions of time under 37 CFR 1.136 are available. Failure to respond will result in the application for patent term extension being dismissed as untimely under section 156(d)(1).

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
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By FAX: (571) 273-0100
Attn: Office of Patent Legal Administration

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg 51, Rm. 6222
Silver Spring, MD 20993-0002

Attn: Beverly Friedman

RE: BEYAZ™
(drospirenone, ethinyl estradiol, levomefolate calcium)

FDA Docket No.: FDA-2011-E